

excess length of sheath **100** or **200** is drawn up and becomes gathered **105** adjacent the first guide section (FIGS. **1B** and **2C**). While continuing to hold catheter introducer **15** in place against the urethral opening, the user's grasp on catheter **90** through sheath **100** or **200** is repeatedly repositioned, as necessary, for gently urging the hydrophilic catheter **90** out of the introducer and into the urethral opening, through the urethra and finally into the bladder for a sufficient distance to permit draining of accumulated urine. Referring to the embodiment shown in FIGS. **2B** and **2D**, tapered portion **25** and neck **26** help to guide the catheter into alignment with aperture **27**. The internal diameters of throughbores **22**, **74**, reservoir aperture **27**, diaphragm aperture **46**, guide tapered inlet **75** and guide outlet **76** are slightly larger than the outer diameter of catheter **90**, so that the catheter, even when thoroughly wetted and slippery, can move slightly radially and can slide longitudinally. The throughbore diameters **22**, **74** are restrictive enough, however, that the catheter introducer **15** prevents a soft, flexible hydrophilic catheter from bending and provides the catheter sufficient rigidity and support to be readily inserted into the urethra. Less flexible hydrophilic catheters may be used satisfactorily with a catheter introducer similar to that shown in FIGS. **7A-B** without the need for the support of a narrow throughbore.

[**0075**] Referring now to FIGS. **8** and **9**, a urine collection bag may be attached to the catheter and may include calibrated volume markings **132** for providing an accurate urine output volume measurement, and/or the bag may include a urine sampling port **134** for withdrawing a specimen for analysis (FIG. **8**). Alternatively, if a basic introducer/catheter/sheath assembly as shown in FIGS. **1A-B** is employed, the user attaches the catheter's urine outlet to a suitable collection container or otherwise provides for urine disposal.

[**0076**] As necessary, the catheter introducer is held in place at the urethral opening and the catheter is supported through the sheath until completion of urine evacuation and removal of the catheter. The catheter is withdrawn from the urethra essentially by reversing the insertion procedure, to resume the catheter's pre-use position inside the first guide section and sheath. After withdrawal, the catheter is again held in place within the first guide section and the sheath, where it is prevented from slipping into a urine collection vessel. The unit is easily disposed of in a sanitary manner. The entire catheterization process can usually be accomplished in about 5 minutes or less.

[**0077**] Using the new catheter device provides for better lubrication of the catheter to reduce the discomfort or irritation typically associated with urethral catheterization. Spillage of liquids used to wet the hydrophilic catheter is avoided. This device is also an improvement over other unitized catheter assemblies in that it provides more options for the user, such as elimination of the need for a lubricant gel and disposal of waste in a conventional toilet. Exemplary embodiments also provide for accurate measurement of urine output using conventional containers without having to first open a collection bag, and collection of a specimen for analysis. It is more adaptable for use in the home or in a public restroom, and lends itself more readily for use in self-catheterization. The catheterization procedure and above-described device enable the user to easily maintain sterile technique to avoid introduction of microbial contaminants into the upper urethra and bladder. Also, the new

catheterization device provides a degree of protection to medical personnel from directly contacting a catheter that may have been exposed to body fluids possibly contaminated with virus. The catheter device exemplified herein can be manufactured economically for use by hospitals, emergency care facilities, nursing homes, rehabilitation centers and the like.

[**0078**] The foregoing disclosure of the exemplary embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure. The scope of the invention is to be defined only by the claims appended hereto, and by their equivalents.

[**0079**] Further, in describing representative embodiments of the present invention, the specification may have presented the method and/or process of the present invention as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims. In addition, the claims directed to the method and/or process of the present invention should not be limited to the performance of their steps in the order written, and one skilled in the art can readily appreciate that the sequences may be varied and still remain within the spirit and scope of the present invention.

What is claimed is:

1. A urinary catheterization device comprising:

- a catheter introducer comprising a first guide section including an inlet for receiving a urinary catheter tip and a second guide section including an aperture for releasing said catheter tip, and, optionally, a removable aperture cover, said aperture adapted for contacting a urethral opening;
- a hydrophilic catheter comprising a tip having at least one urine inlet, a urine outlet, and an outer surface, at least a urethra-insertable portion of said outer surface being hydrophilic, and said tip being initially disposed in said first guide section;
- a flexible walled sheath comprising first and second ends, a lumen, and a length that is less than that of said catheter, said sheath first end being sealingly attached to said catheter at a non-urethra-insertable location on said catheter adjacent to said urine outlet, and said sheath second end being sealingly attached to said first guide section, whereby said catheter tip is initially retained in said first guide section and prevented from slipping into said sheath lumen, and at least said urethra-insertable portion of said catheter being enclosed in said sheath lumen, said sheath lumen adapted for containing a liquid for wetting said enclosed portion of said hydrophilic catheter; and
- a diaphragm disposed in said catheter introducer between said first and said second guide sections, and adapted